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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,528	05/13/1998	SATOSHI KOIZUMI	766.20	2408
5514	7590	10/09/2003	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			RAO, MANJUNATH N	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/068,528

Applicant(s)

KOIZUMI ET AL.

Examiner

Manjunath N. Rao, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,5,15-20 and 72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,15-20 and 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1, 5, 15-20, 72 are currently pending and are present for examination.

Applicants' amendments and arguments, supplemental amendment filed on 8-1-03 and 8-11-03, respectively, have been fully entered and considered, and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### ***Withdrawal of Final rejection***

In view of applicants arguments and remarks Examiner has withdrawn the previous Final rejection of above claims and a new non-final Office action follows.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 15, 16, 18-20 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akihiko et al. (EP 0553821A1, 4-8-93), Kuehn et al. (J. Bacteriol., Vol. 120(3):1151-1157, 1974). Claims 1, 5, 15, 16, 18-20 and 72 are drawn to a method of producing GDP-sugar or UDP-sugar which comprises selecting as enzyme sources a) a culture broth of a microorganism (such as *C.ammoniagenes*) capable of producing GTP or UTP from a nucleotide precursor, b) a culture broth, culture supernatant etc. of a microorganism having

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genes responsible for production of GDP-sugar or UDP-sugar from a sugar selected from a group consisting of glucose, fructose, galactose, sialic acid etc., allowing the enzyme sources the nucleotide precursor and the sugar to be present in an aqueous medium to form and accumulate the sugar-nucleotide and recover the same.

Akihiko et al. teach the synthesis of UTP using the culture supernatants of microorganism B (*C.ammoniagenes*) which has the capability of converting orotic acid to UDP and or UTP (see page 3 of the reference). By such teachings, it would be obvious to one of skill in the art that microorganism B could be used to accumulate the UTP for further use.

Kuehn teaches that cultures of slime mold *P.polycephalum* produce and accumulate UDP-glucose synthesizing enzyme, UDP-glucose pyrophosphorylase and that this enzyme accumulates within the first 8-10 hours of spherule formation. (Apart from Kuehn Examiner was able to find a number of other reports disclosing the microorganism source for UDP-glucose or GDP-glucose).

While the reference by itself does not teach that such an enzyme could be used in a process for making UDP-glucose, it would have been obvious to those skilled in the art, especially those interested in developing a simple and cost-effective method of preparing UDP-sugar, to develop a process for making UDP-glucose by a) selecting as enzyme source the culture broth or cell extract of microorganism B of Akihiko et al. (which produces UTP starting from orotic acid) and b) the culture broth or cell extract of *P.polycephalum* which produces the enzyme (UDP-glucose pyrophosphorylase) required for production of UDP-glucose using UTP and glucose, and allowing the enzyme sources the nucleotide precursor and the sugar to be present in an aqueous medium to form and accumulate UDP-sugar such as UDP-glucose.

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One of ordinary skill in the art would have been motivated to do as other methods to produce the same sugar-nucleotide is either cumbersome or not cost-effective. One of ordinary skill in the art would have a reasonable expectation of success since the reference of Akihiko et al. explicitly teach and provide the required microorganisms to produce UTP from a cheap substrate such as orotic acid and Kuehn provide a source for an enzyme to produce UDP-glucose from an inexpensive starting material. Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office action, applicants have amended claim 1, specifically claiming a method of making UDP-glucose or GDP-glucose. Applicants have also argued that the reference provided by the Examiner teaches a sialic acid synthase which forms sialic acid from CTP and sialic acid wherein the enzyme directly converts sialic acid into sugar nucleotide CMP-sialic acid and that on the other hand the synthase of GDP-sugar or UDP-sugar is an enzyme which forms GDP-sugar from GTP or UTP and a sugar-1-phosphate and that claim 1 relates to a process for producing GDP-sugar or UDP-sugar without using a direct substrate of a sugar-nucleotide synthase, i.e., without (an expensive) sugar-1-phosphate, but using a simple sugar such as glucose which is not a direct substrate of a sugar nucleotide synthase.

In view of applicants amendments and remarks, Examiner has withdrawn the final rejection and now provided a new non-final action rejecting the above claims as obvious.

### ***Conclusion***

### ***Conclusion***

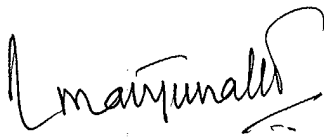
None of the claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

  
**MANJUNATH RAO**  
**PATENT EXAMINER**

Manjunath N. Rao  
October 6, 2003